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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,427	10/22/1998	STEFAN LUKAS	4804-4	3113

7590 02/23/2005

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NEW YORK, NY 10176

EXAMINER

MITCHELL, GREGORY W

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/177,427

Applicant(s)

LUKAS ET AL.

Examiner

Gregory W Mitchell

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 16-30.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuing Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).
13. ☐ Other: _____.


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Please note that this Advisory Action vacates the Advisory Action dated February 08, 2005. Examiner inadvertently indicated claims 16-30 as allowed on the cover sheet. Given the entirety of the Advisory Action it is clear, however, that Examiner intended to maintain the rejection of claims 16-30.

Continuation of 11.

Applicant's arguments are not persuasive. The 35 U.S.C 103 rejections of the Office Action dated October 04, 2004 is maintained.

Applicant's argument, "when these batches of particles were subjected to the process described, it was found that the needle shaped particles produced a material where 19% of the material was released after 40 minutes which is unacceptably high." This argument is not persuasive because the instant claims are to a product, not a process or a product by process.

Likewise, Applicant's argument, "the spray drying process as described in the present application as understood by one skilled in the art involves the dispersion of the active constituents and the polymeric coating in a solvent followed by evaporation of the solvent through the use of a spray dryer," is not persuasive because the claims are directed to a product, not a process or a product by process.

It is noted that if the product claims of the instant application were amended to read as product by process claims, the claims would remain rejected absent a showing of unexpected results.

Applicant argues that Batch D4427 exhibited a sustained release not illustrated by any of the embodiments disclosed by Morella. It is noted that the release rate of Batch D4427 was 8% after 40 minutes whereas the release rate of disclosed in Morella when utilizing dry air for the spray drying process (See Example 5 and Figure 6), the release rate was approximately 15-16% after 40 minutes. Examiner has relied on Douglas et al. to further show that it is known to utilize spherical particles. In particular, it is noted that Douglas et al. teaches that irregular shaped particles reduce the effectiveness of subsequent coating processes (col. 5, lines 8-15). Accordingly, it is Examiner's position that the results achieved by utilizing particles with the aspect ratio of the instant invention are not unexpected.

Applicant argues that because Douglas et al. teaches coating weights substantially higher than instantly claimed and a different coating process (i.e. one that includes coating of the particle with a lipid phase), it is, therefore, not applicable. This argument is not persuasive because the statement in Douglas et al. that irregular shaped particles reduce the effectiveness of subsequent coating processes is not conditional upon the amount of coating used or the method of coating. Regardless of the amount of coating administered to a particle, one of ordinary skill in the art would have realized that irregularly shaped particles would reduce the effectiveness of the coating.

Applicant's arguments regarding the amount of coatings taught by Morella are not persuasive. First, it is noted that Example 6 does not work in accordance with the reference because it is only used to compare how the teaching of Morella is an improvement over the prior art. It is further noted that each of the exemplifications of Morella, for which data is provided, utilizing dry air for spray drying are observed to have improved sustained release properties over the prior art. Accordingly, there is no reason to believe that the range taught to be effective by Morella would not be functional. Applicant's arguments to the unexpected results of the instant invention as compared to Example 5 of Morella has been addressed above.

Applicant's arguments with regard to Yajima et al. and Lu et al. are not persuasive because Examiner only relies on the references to show that it is desirable to mask the taste of clarithromycin and that clarithromycin is suitable for administration in particles containing a polymer coating.

Applicant's arguments that the combination of the references is improper because the references list different techniques is not persuasive. Both Morella and Douglas et al. are drawn to coated drug particles and are, therefore, of an analogous art and properly combined.

Examiner finds the declaration by Lukas insufficient because, as addressed above, a decrease in rate of release by about half when compared to the closest teaching of Morella is not unexpected in view of the teaching of Douglas et al. that irregular shaped particles reduce the effectiveness of the coating processes. It is noted, however, that the declaration is improper because when relying on comparative testing, the Applicant is under a duty to compare his claimed invention to the closest prior art. The declaration of Lukas compares only batch materials prepared under conditions described by his own application and not those of the closest prior art (Morella). For these reasons and the fact that Examiner addressed the declaration in the Final rejection, finality of the Office Action dated October 04, 2004 is deemed proper.